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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

Susan S. Schultz and Russ Schultz

-Plaintiffs-

v.

Merck Sharp & Dohme Corp.

-Defendant-

CIVIL ACTION NO. 3:10-CV-03545-  
GEB-LHG

Hon. Garrett E. Brown, Jr.

**ANSWER AND AFFIRMATIVE  
DEFENSES OF MERCK SHARP &  
DOHME CORP.; DEMAND FOR  
JURY TRIAL**

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Defendant, Merck Sharp & Dohme Corp. (“Merck”), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

**PARTIES**

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1.
2. Merck admits the allegations of Paragraph 2.

### **JURISDICTION**

3. The allegations of Paragraph 3 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 3, except admits, for jurisdictional purposes only, that the Plaintiffs seeks in excess of \$75,000.

4. The allegations of Paragraph 4 are conclusions of law to which no response is required. To the extent a response is required, Merck denies the allegations of Paragraph 4.

### **OPERATIVE FACTS**

5. Merck denies each and every allegation of Paragraph 5, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

6. Merck denies each and every allegation of Paragraph 6, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

7. Merck denies each and every allegation of Paragraph 7, except that Merck admits that it sought and, in 1995, first obtained U.S. Food and Drug Administration ("FDA") approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 7 inconsistent with that prescribing information.

8. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for

prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 8 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia and Bondronat and denies any allegations in Paragraph 8 with respect to Aredia and Bondronat inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 8.

9. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 9.

10. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 10.

11. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 11.

12. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 12, except that Merck denies that there is any causal connection between FOSAMAX® and Plaintiff's alleged injuries.

13. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 13.

14. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15, except that Merck states that it is without knowledge as to Plaintiffs' beliefs.

16. Merck denies each and every allegation of Paragraph 16, except that Merck states that it is without knowledge as to Plaintiffs' beliefs.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information, and that Merck collects information on adverse experiences that are temporally associated with a patient's treatment with FOSAMAX® and reports those adverse experiences to the FDA without regard to whether FOSAMAX® or some other medications or conditions caused such adverse experiences. Merck denies any allegations inconsistent with its published prescribing information. Merck further denies that there is any causal connection between FOSAMAX® and any adverse experience reports of hardness, brittleness, or fracturing of bone, or between FOSAMAX® and Plaintiff's alleged injuries.

19. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 19, except that it admits that Schneider published an article entitled, "Should Bisphosphonates Be Continued Indefinitely? An Unusual Fracture in a Healthy Woman on Long-Term Alendronate," Geriatrics, Jan;61(1):31-3 (2006) and respectfully refers the Court to said article for its actual language and full text.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23, except that Merck admits that Fosamax product sales in 2008 amounted to approximately \$1.55 billion.

24. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies the remaining allegations in Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

34. The allegations of Paragraph 34 state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 34 and respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

**COUNT I**  
**PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-2 et seq.)**

37. Merck repleads its answers to Paragraphs 1 through and including 36, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

38. Merck denies each and every allegation of Paragraph 38, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. To the extent that the allegations of Paragraph 38 are conclusions of law, no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**COUNT II**  
**PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 et seq.)**

45. Merck repleads its answers to Paragraphs 1 through and including 44, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

46. Merck denies each and every allegation of Paragraph 46, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49, except that Merck states that it is without knowledge as to the manner in which Plaintiff utilized FOSAMAX® and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

50. Merck denies each and every allegation of Paragraph 50.

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**COUNT III**  
**PUNITIVE DAMAGES UNDER THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1)**

54. Merck repleads its answers to Paragraphs 1 through and including 53, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**COUNT IV**  
**LOSS OF CONSORTIUM**

58. Merck repleads its answers to Paragraphs 1 through and including 57, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

59. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**ADDITIONAL DEFENSES**

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts



said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiffs' Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

**FIRST ADDITIONAL DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND ADDITIONAL DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

**THIRD ADDITIONAL DEFENSE**

This case is more appropriately brought in a different venue.

**FOURTH ADDITIONAL DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH ADDITIONAL DEFENSE**

Plaintiffs are barred from recovering against Merck because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by applicable federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq.

**SIXTH ADDITIONAL DEFENSE**

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to its prescribing physician. To the extent that New Jersey law is found to apply to Plaintiffs' claims, Plaintiffs' claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warning to prescribing physicians.

**SEVENTH ADDITIONAL DEFENSE**

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned or reduced in accordance with the applicable law.

**EIGHTH ADDITIONAL DEFENSE**

The injuries and damages, if any, sustained by Plaintiffs resulted in whole or in part from their own contributory or comparative negligence and any damages recovered should be reduced and/or barred in accordance with the applicable law.

**NINTH ADDITIONAL DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or

exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**TENTH ADDITIONAL DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH ADDITIONAL DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

**TWELFTH ADDITIONAL DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH ADDITIONAL DEFENSE**

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH ADDITIONAL DEFENSE**

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH ADDITIONAL DEFENSE**

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH ADDITIONAL DEFENSE**

To the extent that Plaintiffs seek punitive damages, such claims are barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST ADDITIONAL DEFENSE**

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND ADDITIONAL DEFENSE**

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-THIRD ADDITIONAL DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-FOURTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred in whole or in part by failure to prevent or mitigate damages.

**TWENTY-FIFTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH ADDITIONAL DEFENSE**

With respect to each and every cause of action, Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

**TWENTY-SEVENTH ADDITIONAL DEFENSE**

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH ADDITIONAL DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH ADDITIONAL DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States of America and the Constitutions of the State of New Jersey and the State of Texas.

**THIRTIETH ADDITIONAL DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST ADDITIONAL DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND ADDITIONAL DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD ADDITIONAL DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH ADDITIONAL DEFENSE**

Plaintiffs have not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH ADDITIONAL DEFENSE**

Plaintiffs have not suffered any actual injury or damages.

**THIRTY-SIXTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred under the doctrine of economic loss.

**THIRTY-SEVENTH ADDITIONAL DEFENSE**

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiffs for any amounts received from collateral sources.

**THIRTY-EIGHTH ADDITIONAL DEFENSE**

Plaintiffs' claims of fraud are not pleaded with the required particularity.

**THIRTY-NINTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including FOSAMAX®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

**FORTIETH ADDITIONAL DEFENSE**

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

**FORTY-FIRST ADDITIONAL DEFENSE**

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiffs.



**FORTY-SECOND ADDITIONAL DEFENSE**

To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**FORTY-THIRD ADDITIONAL DEFENSE**

To the extent that New Jersey law applies to Plaintiffs' claims and to the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any source for injuries in the Complaint, such benefits are not recoverable in this action under N.J.S.A. 2A:15-97.

**FORTY-FOURTH ADDITIONAL DEFENSE**

The defendant is not guilty of negligence and violated no duty owing to Plaintiffs.

**FORTY-FIFTH ADDITIONAL DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack capacity and/or standing to bring such claims.

**FORTY-SIXTH ADDITIONAL DEFENSE**

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

**FORTY-SEVENTH ADDITIONAL DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, res judicata, payment and/or release.

**FORTY-EIGHTH ADDITIONAL DEFENSE**

Plaintiffs' damages are barred or reduced by the doctrine of avoidable consequences.

**FORTY-NINTH ADDITIONAL DEFENSE**

With respect to Plaintiffs' demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 116 U.S. 1589 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mut. Auto. Ins. Co. v. Campbell, 123 S.Ct. 1513 (U.S. 2003).

**FIFTIETH ADDITIONAL DEFENSE**

To the extent that Plaintiffs attempt to seek equitable relief, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

**FIFTY-FIRST ADDITIONAL DEFENSE**

Plaintiffs are barred from recovery and/or Plaintiffs' recovery is limited pursuant to the Comparative Negligence Act, N.J.S.A. 2A:15-5.1, et seq. to the extent that New Jersey law applies to Plaintiffs' claims.

**FIFTY-SECOND ADDITIONAL DEFENSE**

Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiffs, then it shall only be liable for its equitable share of Plaintiffs' recovery since any liability which would be found against it will be insufficient to impose joint liability. In the alternative, the liability, if any, of Merck is limited by and pursuant to the New

Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, et seq. to the extent that New Jersey law applies to Plaintiffs' claims.

**FIFTY-THIRD ADDITIONAL DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel or waiver.

**FIFTY-FOURTH ADDITIONAL DEFENSE**

To the extent that New Jersey law applies to Plaintiffs' claims, Merck asserts all defenses available to it pursuant to N.J.S.A. 2A:58C-1, et seq., otherwise known as the New Jersey Product Liability Act.

**FIFTY-FIFTH ADDITIONAL DEFENSE**

To the extent that New Jersey law applies to Plaintiffs' claims, those claims are confined to those available under the New Jersey Product Liability Act.

**FIFTY-SIXTH ADDITIONAL DEFENSE**

Venue in this case may be improper under R. 4:3-2.

**FIFTY-SEVENTH ADDITIONAL DEFENSE**

New Jersey law does not apply to any claim that can be or is asserted by Plaintiffs.

**FIFTY-EIGHTH ADDITIONAL DEFENSE**

This case may be subject to dismissal or stay on the grounds of *forum non conveniens*.

**FIFTY-NINTH ADDITIONAL DEFENSE**

The substantive law of Texas applies to Plaintiff's claims.

**SIXTIETH ADDITIONAL DEFENSE**

If Plaintiffs sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiffs and/or of third parties, not from any negligence or breach of duty by Merck. If judgment is rendered in Plaintiffs' favor, the amount of such judgment must be reduced pursuant to the Proportionate Responsibility Statute § 33.001, et seq. of the Texas Civil Practice & Remedies Code.

**SIXTY-FIRST ADDITIONAL DEFENSE**

Merck is unaware at this time of any settlements by any alleged joint tortfeasor. In the event any settlement is or has been made by any alleged joint tortfeasor, however, then Merck is entitled to a full credit, offset, pro rata reduction, or percentage reduction, based on the percentage of fault attributable to each settling party, person, or other entity herein, and Merck makes known to the other parties and to the court that it will avail itself of its rights under §§ 33.012 et seq. of the Texas Civil Practice & Remedies Code.

**SIXTY-SECOND ADDITIONAL DEFENSE**

Merck fully asserts § 82.001 and § 82.007 of the Texas Civil Practice and Remedies Code and states that all of Plaintiffs' claims are barred under those sections.

**SIXTY-THIRD ADDITIONAL DEFENSE**

Any claims for exemplary damages are limited by Section 41.008 of the Texas Civil Practice and Remedies Code to two times the amount of actual damages or \$200,000, whichever is greater. Merck asserts all other defenses and limitations on punitive damages contained in Chapter 41 of the Texas Civil Practice and Remedies Code.

**SIXTY-FOURTH ADDITIONAL DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law without proof of every element beyond a reasonable doubt would violate Merck's rights under Amendments IV, V, VI and XIV of the United States Constitution and under Sections 9, 10, 14 and 19 of Article I of the Texas Constitution.

**SIXTY-FIFTH ADDITIONAL DEFENSE**

Unless Merck's liability for punitive damages and the appropriate amount of punitive damages are each required to be established by clear and convincing evidence under Texas law, any awards of punitive damages would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**SIXTY-SIXTH ADDITIONAL DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because any award of punitive damages under Texas law without bifurcating the trial as to all punitive damages issues would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**SIXTY-SEVENTH ADDITIONAL DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law subject to no pre-determined limit, either a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose would violate Merck's due process rights

guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**SIXTY-EIGHTH ADDITIONAL DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law by a jury that:

- (1) is not provided any standard of sufficient clarity for determining the appropriateness, or the appropriate size of any punitive damages award;
- (2) is not instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment;
- (3) is not expressly prohibited from awarding punitive damages or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics;
- (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; or
- (5) is not subject to judicial review on the basis of objective standards would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**SIXTY-NINTH ADDITIONAL DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law for the purpose of compensating Plaintiffs for elements of damages not otherwise recognized by Texas law would violate Merck's

due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**SEVENTIETH AFFIRMATIVE DEFENSE**

Merck asserts that the determination of the amount of punitive damages, if any, shall be bifurcated from the remaining issues pursuant to *Transportation Ins. Co. v. Moriel*, 879 S.W.2d 10 (Tex. 1994).

**SEVENTY-FIRST ADDITIONAL DEFENSE**

The imposition of punitive damages violates the open courts provision of the Texas Constitution.

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In so much as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees as may be available by law, together with such and other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

Dated: September 27, 2010

**HUGHES HUBBARD & REED LLP**

A NEW YORK LIMITED LIABILITY PARTNERSHIP

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Attorneys for Defendant Merck Sharp &  
Dohme Corp.



**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on September 27, 2010, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system on all counsel of record.

/s/ Wilfred P. Coronato